

National Cancer Institute Seeks Participants for Osteosarcoma Therapy Based on Histologic Response

Study Synopsis	<p>In this pilot study, patients with newly diagnosed osteosarcoma will receive cisplatin/doxorubicin/methotrexate in the neoadjuvant setting. Patients with non-metastatic disease and good response to neoadjuvant therapy will receive additional courses of cisplatin/doxorubicin/methotrexate in the post-surgical setting. Currently, three groups of patients with poor outcome can be identified: 1) metastatic disease, 2) unresectable disease and 3) nonmetastatic disease with poor response to neoadjuvant therapy. Therapy will be intensified with three courses of melphalan/cyclophosphamide in the adjuvant setting for these patients.</p>	
Eligibility Criteria	<ul style="list-style-type: none"> ▪ Newly diagnosed malignant high-grade osteosarcoma of bone ▪ Patients with recurrent and/or progressive disease after therapy on other treatments not containing cyclophosphamide/melphalan are eligible for cyclophosphamide/melphalan with autologous stem-cell rescue. ▪ Age \leq 25 years ▪ ANC \geq 1500/mm³; platelet count \geq 100,000 mm³; hemoglobin \geq 8.0 g/dl ▪ Serum creatinine \leq 1.5 x normal and creatinine clearance/GFR $>$ 70 ml/ min/1.73 m² ▪ Cardiac ejection fraction \geq 45% or shortening fraction \geq 27% ▪ Adequate liver function (total bilirubin \leq 2.0 mg/dl ; ALT $<$ 5 x normal) 	
Exclusion Criteria	<ul style="list-style-type: none"> ▪ Osteosarcoma secondary to radiation or premalignant conditions ▪ Pregnancy ▪ Low-grade, parosteal, or periosteal osteosarcoma 	
Treatment Plan	<ul style="list-style-type: none"> ▪ Cisplatin/doxorubicin/methotrexate given preoperatively (inpatient) ▪ Definitive surgery at week 11 ▪ Good-risk patients receive additional cycles of cisplatin/doxorubicin/methotrexate postoperatively ▪ Poor-risk patients receive cyclophosphamide/melphalan with autologous PBSC postoperatively 	
Study Sites	<p>National Institutes of Health (NIH) Lee Helman, M.D. Pediatric Oncology Branch 301-496-4257</p> <p>Texas Children's Hospital Murali Chintagumpala, M.D. 713-770-4558</p>	<p>Cook Children's Medical Center Jeffrey C. Murray, M.D. 817-885-4020</p> <p>University of Oklahoma Health Sciences Center William Meyer, M.D. 405-271-5311</p>

For more information about this study and other National Cancer Institute clinical studies conducted in Bethesda, Maryland, call the NCI Clinical Studies Support Center at
1-888-624-1937.